11-27-2013

Washington Update: News From our Nation's Capital

Sherine B. Abdul-Khaliq  
American University Washington College of Law

Jit Chatterjee  
American University Washington College of Law

Chandana Kolavala  
American University Washington College of Law

Rebecca Wolf  
American University Washington College of Law

Follow this and additional works at: http://digitalcommons.wcl.american.edu/hlp

Part of the Health Law Commons

Recommended Citation
Congress Fails to Override President’s Veto of SCHIP Bill

The State Children’s Health Insurance Program (SCHIP) is a national program which began in 1997. SCHIP provides health insurance for those families who cannot afford private insurance, but whose incomes are not low enough to qualify them for Medicaid. SCHIP was created in an effort to quell the rising numbers of children lacking health coverage.

SCHIP is a partnership between federal and state governments. Each state runs its program pursuant to provisions issued by the Center for Medicare and Medicaid Services (CMS). SCHIP gives states the flexibility to design their programs separately from Medicaid, use funds from SCHIP to expand their Medicaid program, or combine SCHIP and Medicaid. According to CMS, SCHIP covered 6.9 million children in 2006.

Despite the successes of the SCHIP program, the number of uninsured children continues to rise; several states have not had sufficient funding to successfully implement the program. The federal law authorizing SCHIP expired in September 2007. Until the bill is reauthorized, no new federal SCHIP funds will be made available for the upcoming and future fiscal years. This fall, both the House and the Senate passed a bipartisan measure to expand the program under H.R. 976. The proposed bill, the Children’s Health Insurance Program Reauthorization Act of 2007, would expand coverage to include more than 4 million additional participants over the next five years. The bill also called for a $35 billion budget increase for five years, increasing SCHIP spending to $60 billion through 2010. Under the bill, the expansion of the SCHIP program would be funded by a nationwide tax increase of 61 cents per cigarette pack.

On October 3, 2007, President Bush vetoed the reauthorization of the legislation, claiming that enactment of the bill would lead to health care federalization and expand SCHIP beyond its original purpose. President Bush stated he would be open to a compromise, but would not agree to endorse a proposal that would expand the number of children covered by SCHIP. On October 18, 2007, the House fell 13 votes short (273-156) of the two-thirds majority required to override the President’s veto. On October 25, 2007, the House passed a revised version of the vetoed bill, with a vote of 265-142. However, the subsequent revised version was seven votes short of overriding the President’s veto.

The revised bill maintained the $35 billion expansion proposed in the first version, but also was amended to include concessions to some of the President’s objections. The added provisions include making illegal immigrants ineligible for coverage, and phasing adults out of the program one year earlier than had been proposed in the original bill. Notably, the cigarette tax, which Bush also opposed, was reintroduced in the revised bill in spite of the President’s objection. Despite the noted concessions in the bill, it is expected that President Bush’s veto will not be overturned.

OIG Releases Report on FDA’s Oversight of Clinical Trials

Before being introduced into the marketplace, federal law requires that all new drugs and medical devices are to be tested in clinical trials to ensure their safety and effectiveness. The Food and Drug Administration’s (FDA) oversight of clinical trials ensures that those responsible for conducting or overseeing clinical trials – sponsors of a new drug or medical device, clinical investigators, and institutional review boards (IRB) – comply with regulations designed to advance the public’s health and protect the rights, safety, and well-being of study participants.

Prompted by a congressional inquiry regarding weaknesses in the FDA’s oversight of clinical trials and a series of news articles expressing similar concerns, the Office of the Inspector General (OIG), Department of Health and Human Services, carried out a two-pronged review to (1) determine the extent to which the FDA conducted inspections of clinical trials during fiscal years (FY) 2000-2005, and (2) assess the FDA’s process for inspecting clinical trials.

In a report released September 2007, the OIG concluded that the FDA’s efforts to effectively oversee clinical trials were hampered by a lack of data and departmental coordination. The agency did not know how many clinical trials were on-going, or how many clinical trial sites were involved. The FDA was also unable to identify all IRBs. Using data extrapolated from other government sources, the OIG estimated that of the likely 350,000 clinical trial sites associated with new drugs or medical devices, the FDA inspected less than...
one percent of these sites between FY 2000-2005. In addition, the OIG found that most of the FDA’s inspections focused on completed trials rather than the on-going trials where human subject protection was most critical. There were also inconsistent classifications of the violations found at trial sites and, in many cases, the most serious violations were downgraded to less serious classifications. To further exacerbate the problem, the FDA’s guidance and regulations for clinical trials are outdated, and do not address the complexities of large clinical trials involving multiple sites within and outside of the United States.

The OIG identified several important steps that the FDA should take to improve its oversight of clinical trials, including: (1) develop a clinical trial database that includes all clinical trials; (2) create an Institutional Review Board registry; (3) create a cross-center database that allows for complete tracking of FDA inspections; (4) establish a mechanism to provide feedback to investigators on their inspection reports and findings; and (5) seek legal authority to provide oversight that reflects current clinical trial practices.

To read the complete OIG report visit: www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf.

Creating a Private Cause of Action for Healthcare Privacy Violations

The Health Insurance Portability and Accountability Act (HIPAA), more commonly known as the HIPAA Privacy Rule, has increased the prominence of patient privacy as a health law issue. However, since HIPAA became effective in 2003, the U.S. Department of Health and Human Services (HHS) has not imposed any civil monetary penalties for HIPAA violations. HIPAA’s enforcement authority is limited to action by the HHS Office of Civil Rights, and no private or state-based litigation is sanctioned under the current regulations. This has led to concerns about the effectiveness of HIPAA’s current enforcement approach – an approach that has focused on voluntary compliance, corrective actions, and resolution agreements. In an effort to improve HIPAA’s enforcement scheme, Senators Patrick Leahy (D-VT) and Edward Kennedy (D-MA) introduced the Health Information Privacy and Security Act of 2007 (HIPSA), or Senate Bill 1814, a new healthcare privacy bill designed to provide more stringent privacy standards and safeguards in addition to harsher civil and criminal penalties for privacy violations.

One of the notable provisions of HIPSA would alter the existing privacy framework by creating a private right of enforcement for patients who suffer healthcare privacy violations under HIPAA. Under this proposal, individuals could stand to receive compensatory damagers, attorney’s fees, and punitive damages for certain blatant violations. Perhaps as significantly, HIPSA would extend the existing enforcement authority to the State Attorney General’s offices and any local agencies they recognize. The State Attorney General’s offices and other authorities given permission to do so will specifically be permitted to file a civil action in federal district court as a means of potentially obtaining civil penalties from entities that fail to adequately protect patients’ privacy rights. HIPSA would override any inconsistent provisions of HIPAA.

For the moment, the bill has stalled after being referred to the Committee on Health, Education, Labor, and Pensions. HIPSA has received sparse public attention and support so far, but this could easily change if one of the presidential candidates takes a stance on this proposal. The Bush administration has not expressed any interest in this bill, which was expected since bill implies the current administration’s approach to HIPAA enforcement is failing. Given its progressive construction, HIPSA’s eventual passage in any form may depend on which party succeeds in winning the Presidency in 2008.

Small Business Healthcare Reform

The Senate Finance Committee has recently considered expanding health care coverage for employees of small businesses. The recent Senate hearing covered the following topics: making coverage more portable; creating association health plans; reducing the cost of individual market coverage; and creating health care tax credits.

Half of the nation’s 47 million uninsured citizens work for small businesses. Continually increasing healthcare costs negatively and disproportionately affect small businesses. One proposal to address this problem includes arranging for small companies to coalesce with other small businesses for the limited purpose of purchasing an insurance policy, thereby spreading risks associated with health care costs across a larger pool of employees. However, critics of this proposal note that member companies who have healthier employees will not likely be amenable to a plan of this nature.

Presidential candidates from both parties have released proposals for healthcare reform. Senator Hillary Clinton (D-NY) proposes a health care plan which will require all Americans to obtain insurance. Her plan will offer tax breaks to small companies and subsidies for low-income individuals. Senator Barack Obama (D-IL) proposes a national health care plan similar to the insurance plan that federal employees are currently entitled to receive. Former Senator John Edwards (D-NC) suggests a plan that includes combining insurance pools, tax credits, and expanding the Medicare Program.

Republican candidates tend to propose health care reforms that favor tax credits over government subsidies. Former New York Mayor Rudy Giuliani proposes expanding health savings accounts. Former Massachusetts Governor Mitt Romney proposes deregulating the private insurance market in an effort to drive down premiums. Senator John McCain (R-AZ) proposes allowing insurers to cover individuals who move from state-to-state.

Regardless of which plan may be implemented in the future, experts predict that no changes will be made to current health care policy until after the presidential election in November 2008.

Sherine B. Abdul-Khaliq, Jit Chatterjee, Chandana Kolavala, and Rebecca Wolf contributed to this column.